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| APPLICATION NO.              | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|------------------------------|-------------|----------------------|---------------------|------------------|
| 10/629,259                   | 07/29/2003  | Craig A. Hamilton    | 9151-26             | 6693             |
| 20792                        | 7590        | 01/10/2008           |                     |                  |
| MYERS BIGEL SIBLEY & SAJOVEC |             |                      | EXAMINER            |                  |
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| RALEIGH, NC 27627            |             |                      |                     |                  |
|                              |             |                      | ART UNIT            | PAPER NUMBER     |
|                              |             |                      | 3737                |                  |
|                              |             |                      | MAIL DATE           | DELIVERY MODE    |
|                              |             |                      | 01/10/2008          | PAPER            |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                                      |  |  |
|------------------------------|--------------------------------------|--|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/629,259 | <b>Applicant(s)</b><br>HAMILTON ET AL. |  |
|                              | <b>Examiner</b><br>A. Lauritzen      | <b>Art Unit</b><br>3737                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11 September 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claims 1-20, 24, 25, 29, 30 and 32 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. For example, claim 1 now specifies “displaying a plurality of the adjusted MRI cine loops at a clinician workstation in substantially real-time *while the patient is in an MRI scanner* used for the acquiring step,” but this was not clearly pointed out in Applicant’s disclosure. Paragraph 49 details near real-time display, and it can be inferred that *perhaps* the patient remains in the scanner while the clinician views the cine loops, but this is not necessarily inferred from the description of the invention. The disclosure is not specific to the details of the patient or scanner. While the specification does make mention of real-time display, any details beyond this are not reasonably inferred. The statements added to claim 1 (and claim 32) specifying display “during the stress test” to “adjust parameters... to avoid injury” are also not wholly supported by applicant's disclosure and there is no reasonable expectation for such details to be inferred.

2. Claim 29 details registering a common physical location of the heart in the MRI cine loops before the step of comparing, but registration of loops is neither described in relation to common physical locations of the heart, nor is it specified to take place prior to comparison.

***Response to Arguments***

Applicant's arguments filed 11 September 2007 have been fully considered but they are not persuasive and/or are moot in view of new grounds of rejection.

Applicant asserts that claim 1 distinguishes from Lobodzinski in that "cine loops are displayed during the stress test to allow a physician to assess cardiac physiology of a patient so as to adjust parameters to test and/or avoid injury...". Examiner corresponds this argument to the feature reciting real-time display "while the patient is in an MRI scanner" which is rejected under the first paragraph of 35 U.S.C. 112 as not being adequately supported by applicant's disclosure (above section 1), but regardless these additional features argued are not in applicant's claims and can most closely be corresponded merely to real-time display, of which Lobodzinski expressly teaches in the abstract and other passages. Examiner additionally points out that the cine loops (or equivalent media known to skilled artisans) are also viewable during administration of the stress test. For the foregoing reasons, at least claim 1 is not patentably distinct from Lobodzinski and therefore the rejection is maintained and repeated herein below.

**DETAILED ACTION**

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 1-10, 12-19, 25-27, 28-29 and 31-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lobodzinski (US 5,619,995) in view of Epstein et al. (US 5,997,883).

Lobodzinski discloses a system for used with diagnostic imaging systems for the acquisition, display, and processing for enhanced visualization of data in real-time while a patient is undergoing a cardiac stress test. Although much of the disclosure is directed to an ultrasound system, other systems may be used such as a "cardiac Magnetic Resonance Imaging apparatus" (col. 8, line 10). Lobodzinski states that although most diagnostic imaging systems provide some sort of cine loop review (col. 2, line 4), they typically do not provide without the additional processing and display that Lobodzinski discloses. The analog and/or digital inputs (cine-loops included) are adjusted based on heart rate where the number of frames obtained is based on the heart period (col. 13, line 15; also col. 11, lines 33-50). Two or more such loops may be synchronized and simultaneously displayed. Frames may be removed from the slower heart rate loop so that the cycles will be displayed simultaneously (col. 13, lines 24-35) so that the temporal placement of the frames in each cycle are the same and therefore each cycle has the same number of frames (figure 7). Lobodzinski states that cycle synchronization is important in stress testing, as patient management decisions are made from visual assessment of the motion displayed simultaneously (col. 13, lines 1-36 for temporal synchronization). Simultaneous side-by-side comparisons may be used during examination for diagnostic purposes (col. 1, lines 61-65). Workstation features of selecting dose amount(s), alternate view(s) and rapidly switching between displays are well known to those of ordinary skill in the art and it would be obvious to incorporate them in order to yield expected results of ease of use and enhanced visibility of physiologic data.

Stress studies are done consisting of two or more sets of, for example pre- and post-exercise, cardiac imaging data (col. 5, line 10). The pre-exercise data establishes a baseline

dataset. Comparison may also be made between different locations, or projections, of the heart during the same study (col. 13, lines 8-10). Additionally, characteristics of the loops may be adjusted, including editing functions (col. 12, line 17). The size of the display area and the frame rate may be adjusted for one or more loops (col. 12, lines 60-65). When more than one loop is selected for display, the display area is automatically adjusted and the size of all of the frames in the selected loop, as well as those in the other loop are adjusted as well (col. 12, lines 38-42 and figure 6). The adjustments of Lobodzinski are real time, and the system is compatible with known digital and analog input formats (col. 11, lines 32-34; also line 45 for real time). Single frame manipulation is disclosed at col. 11, line 59 – col. 12, line 17, and also at line 31. The manipulation techniques of Lobodzinski are real-time capable (Abstract), with “compression performed in less than x-milliseconds” (col. 3, lines 63-64) and real-time video and audio compression/decompression and temporal domain processing (col. 4, lines 40-43).

Lobodzinski discloses all features of the invention as substantially claimed as detailed above, but does not specify acquiring a plurality of different views or selecting one of a dose amount, a view, or at least one dose amount and at least one view; however, in the same field of endeavor, Epstein et al. (US 5,997,883) disclose showing the heart at different phases of its cycle or at different slice locations which are different anatomical views (col. 1, lines 45-47). Epstein et al further disclose selecting views from each heartbeat based on cardiac phase (Abstract). It would have been obvious to one of ordinary skill in the art at the time of invention to acquire multiple anatomical views, as taught by Epstein et al, with the system of Lobodzinski in order to correlate each time-stamped view with a phase of the cardiac cycle (Epstein, col. 4, lines 51-57).

Regarding claims 25 and 31, Epstein discloses identification of systole without MR fluoroscopy (Fig. 2; equation at col. 4, line 48; col. 3, lines 49-53). Epstein further discloses acquiring images on a patient with a heart rate of 60 bpm (col. 3, line 21; also col. 7, lines 44-45 and line 67) with a temporal resolution of 48 msec (that is, according to the equation(s) at col. 2, line 57-67, with 8 views per segment disclosed as commonly used in the art and a TR of 6 ms disclosed at col. 6, line 36). The scan of Epstein is accomplished within a single breathhold (or about 16 heart beats, disclosed at col. 2, line 44, which at a heart rate of 60 bpm corresponds to a breathhold duration of about 16 seconds).

Regarding claims 28 and 29, the system of Lobodzinski as appended by Epstein includes all features of the invention as substantially claimed, including acquisition of baseline data (comparison of pre- and post-exercise data for different views is established as conventional in the art by Lobodzinski at col. 5, lines 11-12). Lobodzinski further discloses a processor for automatic comparison of cine loops at different heart rates, including comparison to previously recorded sequences (col. 4, lines 39-44). It would have been obvious to compare to the previously recorded pre-exercise (baseline) sequence for the purpose of evaluating the change induced on the heart prior to and after administering a stress (here, exercise).

Regarding claim 32, the method steps addressed above require an associated workstation.

2. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lobodzinski in view of Epstein et al. as applied to claim 1 above, further in view of Brackett (US 2003/0206646). Lobodzinski as appended by Epstein, as discussed above, discloses selection of which frames to include in the cine loop, for example by removing frames, however fails to explicitly disclose that frames may be added by repeating frames from a cine loop. Brackett also

discloses a system for diagnostic imaging including the use of cine loops for storing and displaying imaging data. Additionally, Brackett discloses that duplicate frames may be inserted between existing frames in order to achieve a given display frame rate (paragraph 29). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the disclosure of Lobodzinski in light of the teachings of the reference by Brackett to add the capability to repeat frames in order to, as Brackett states, achieve smoother transitions, or to provide another way to achieve desired frame rate.

3. Claims 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lobodzinski in view of Epstein et al. as applied to claims 1 and 19 above, further in view of Holloway, et al (US 6500123). Lobodzinski as appended by Epstein et al, as discussed above, discloses synchronizing frame loops, such as a baseline loop and a stress test loop, however fails to disclose registering the two loops. Holloway also discloses a system for comparing images during stress test heart studies and further discloses that images may be aligned through transformation of one data set to the coordinate system of the other, also known as registration, in order to allow differences and similarities between the views to be readily observed. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the disclosure of Lobodzinski in light of the teachings of the reference by Holloway to include registration in order to provide, as Holloway states, improved alignment and to reduce variability in diagnoses (col 1, lines 45-65).

4. Claims 21-24 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lobodzinski in view of Berger et al. (US 2004/0015079) and Song et al. (US 5,680,862).



Lobodzinski, as discussed above, substantially discloses the invention as claimed including adjusting the display size of the loops. However, Lobodzinski fails to explicitly disclose cropping frames to provide a portion of the frame or adjusting one of a contrast, brightness, gamma and opacity characteristic. Song also discloses an imaging system using MRI cine display where the images displayed in the cine loop are cropped to a region surrounding the left ventricle (col. 8, lines 60-65). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the disclosure of Lobodzinski in light of the teachings of the reference by Song in order to including a cropping function to provide improved visualization of details of the heart, such as the left ventricle. Berger et al. disclose an imaging system optionally using MRI cine display with user-adjusted brightness and contrast parameters (pars. 443-444) with preferred touchscreen capability (pars. 143 and 314). It would have been obvious to one of ordinary skill in the art at the time of invention to allow for characteristics such as brightness, contrast and opacity to be adjusted by the user in order to enhance visibility of the display, and to alter those parameters by way of a touchscreen, as taught by Berger et al.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

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will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to A. Lauritzen whose telephone number is (571) 272-4303. The examiner can normally be reached on Monday - Friday, 8:30am - 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian L. Casler can be reached on (571) 272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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